DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

g1614d

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
2001-DT-26

August 14, 2001

Robert Conner, M.D.
Supervising Radiologist
The Imaging Center
7631 W. Jefferson Blvd.
Fort Wayne, IN 46804

Dear Dr. Conner:

We are writing you because on August 2, 2001, your facility was inspected by a representative of the State of Indiana acting in behalf of the Food & Drug Administration (FDA). The inspection revealed serious regulatory problems involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed the following Repeat Level 2 findings at your facility:

1. Corrective actions for processor QC failures were not documented at least once for your mammography film processor.

2. There was no documentation available to show that your radiologic technologist, [redacted] met the continuing education requirement of having completed a minimum of 15 CEU's in mammography within the past 36 month period.

The specific problems noted above appeared on your MQSA Facility Inspection Report (copy enclosed), which your facility personnel received at the close of the inspection. These problems are identified as Repeat Level 2 because they identify a failure to meet a significant MQSA requirement and indicate failure by your facility to implement permanent corrective action of these problems found during your previous inspection.

Because this condition may be symptomatic of serious underlying problems that could compromise

the quality of mammography at your facility, it represents a violation of law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that are also listed on the inspection report provided to your facility personnel at the close of the inspection. These Level 2 findings are:

1. Mammography processor QC records were missing on 2 consecutive days and were also missing for a total of 5 out of 22 days of operation during the month of December, 2000. This represents the records being missing 23% of the days during that month.

2. Corrective action before further exams for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limit, was not documented for the [redacted] mammography unit in Room 1.

The inspector was informed on several occasions during the inspection that there was insufficient time to perform all of the QC duties required for mammography due to their busy schedule. Please be advised that this is not an acceptable reason for the failure to perform all required QC testing or document corrective actions prior to performing mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct the Repeat Level 2 and Level 2 violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations;

- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted)

Please submit your response to: Mr. David M. Kaszubski
Director Compliance Branch
U.S. Food and Drug Administration
1560 East Jefferson Ave.
Detroit, MI 48207

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective actions, you should consider the more stringent State requirements, if any. You should also send a copy to the State of Indiana radiation control office that conducted the inspection referenced in this letter. You may choose to address both the FDA and any additional State requirements in your response.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter only pertains to findings of your inspection and does not necessarily address other obligations you have under law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Dennis E. Swartz, Radiological Health Expert, at 313-226-6260 Ext. 155.

Sincerely yours,

John P. Kempster

for Raymond V. Mlecko
District Director
Detroit District

Enclosures:a/s